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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 877,160	06 08 2001	Hsu Ching-Hsang	12774-003001	1015

7590

11-07-2002

Y. ROCKY TSAO  
FISH & RICHARDSON, P.C.  
225 Franklin Street  
Boston, MA 02110-2804

EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 11 07/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/877,160

Applicant(s)

CHING-HSAING ET AL.

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to a transgenic mammal comprising DNA encoding dust mite antigen SEQ ID NO:1, classified in class 800, subclass 8.
- II. Claims 1-8, drawn to a transgenic mammal comprising DNA encoding dust mite antigen SEQ ID NO:2, classified in class 800, subclass 8.
- III. Claims 1-8, drawn to a transgenic mammal comprising DNA encoding dust mite antigen SEQ ID NO:3, classified in class 800, subclass 8.
- IV. Claims 9-15, drawn to milk comprising the allergen Der p 5, classified in class 426, subclass 580.
- V. Claims 9-15, drawn to milk comprising the allergen Der p 1, classified in class 426, subclass 580.
- VI. Claims 9-15, drawn to milk comprising the allergen Der p 2, classified in class 426, subclass 580.
- VII. Claims 16-20, drawn to a method of treatment using milk comprising the allergen Der p 5, classified in class 424, subclass 439.
- VIII. Claims 16-20, drawn to a method of treating allergies using milk comprising the allergen Der p 1, classified in class 424, subclass 439.
- IX. Claims 16-20, drawn to a method of treating allergies using milk comprising the allergen Der p 2, classified in class 424, subclass 439.

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- X. Claims 21-27, drawn to a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:1, classified in class 536, subclass 23.1.
- XI. Claims 21-27, drawn to a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:2, classified in class 536, subclass 23.1.
- XII. Claims 21-27, drawn to a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:3, classified in class 536, subclass 23.1.
- XIII. Claim 28, drawn to a germ cell comprising DNA encoding the amino acid sequence of SEQ ID NO:1, classified in class 435, subclass 325.
- XIV. Claim 28, drawn to a germ cell comprising DNA encoding the amino acid sequence of SEQ ID NO:2, classified in class 435, subclass 325.
- XV. Claim 28, drawn to a germ cell comprising DNA encoding the amino acid sequence of SEQ ID NO:3, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III are patentably distinct because the structure and function of each protein is different and requires a separate search; therefore, the structure and function of each transgenic mammal comprising DNA encoding each protein is different and requires a separate search.

Groups I-III and IV-VI are patentably distinct because milk having a heterologous non-milk protein can be made by adding the protein to milk and does not require the transgenic mammal. The purpose of the transgenic is to produce the milk, but the purpose of the milk is to treat allergies.

Groups I-III and VII-IX are patentably distinct because the purpose of the transgenics is to make milk while the purpose of the method is to treat allergies. The products and reagents required to make and use the transgenic are materially distinct and separate than those required for the method. The transgenic does not require the method and the method does not require the transgenic.

Groups I-III and X-XII are patentably distinct because the purpose of the transgenic is to make milk while the DNA can be used as a probe. The transgenic of claim 1 does not require the DNA in Groups X-XII and the DNA does not require the transgenics.

Groups I-III and XIII-XV are patentably distinct because the purpose of the transgenic is to make milk while the germ cell is used for fertilization. The transgenic does not require the germ cell and the germ cells do not require the transgenic.

Groups IV-VI are patentably distinct because the structure and function of each protein is different and requires a separate search; therefore, the structure and function of milk comprising each protein is different and requires a separate search.

Inventions IV-VI and VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of treating allergies can be practiced by administering the antigen alone in the absence of milk.

Groups IV-VI and X-XII are patentably distinct because the purpose of the milk is to treat allergy while the DNA can be used as a probe. The protocols and reagents for milk and DNA are materially distinct and separate. The milk does not require the DNA and the DNA does not require the milk.

Groups IV-VI and XIII-XV are patentably distinct because the purpose of the milk is to treat allergy while the germ cell is used for fertilization. The protocols and reagents for milk and germ cells are materially distinct and separate. The milk does not require the germ cells and the germ cells do not require the milk.

Groups VII-IX are patentably distinct because the structure and function of each protein is different and requires a separate search; therefore, treating allergies using milk comprising each protein is different, requires a separate search and requires different considerations regarding enablement.

Groups VII-IX and X-XII are patentably distinct because the purpose of the method is to treat allergy while the DNA can be used as a probe. The protocols and reagents for treating allergies using milk and for DNA are materially distinct and separate. The method does not require the DNA and the DNA does not require the method.

Groups VII-IX and XIII-XV are patentably distinct because the purpose of the method is to treat allergy while the germ cell is used for fertilization. The protocols and reagents for treating allergies using milk and for using germ cells are materially distinct and separate. The method does not require the germ cells and the germ cells do not require the method.

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Groups X-XII are patentably distinct because the structure and function of the 3 DNA sequences is different, produces a different protein and requires a separate search.

Groups X-XII and XIII-XV are patentably distinct because the DNA can be used as a probe while the germ cell is used for fertilization. The protocols and reagents for DNA and germ cells are materially distinct and separate. The DNA does not require the germ cells and the germ cells do not require the DNA.

Because these inventions are distinct for the reasons given above and the search required for the Groups are each separate and distinct, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to \*\*\* on \*\*\* to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

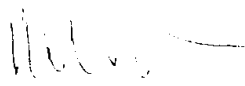
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remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is 703-305-0120. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
MICHAEL C. WILSON  
PATENT EXAMINER